Essai Clinique

Généré le 09 mai 2024 à partir de

Titre	Protocole maître d'essai international adaptatif : Un essai plateforme international prospectif de phase II/III à répartition aléatoire adaptative en fonction des réponses, visant à évaluer plusieurs schémas posologiques dans les cas de GBM nouvellement diagnostiqués et récurrents
Protocole ID	GBM AGILE
ClinicalTrials.gov ID	NCT03970447
Type(s) de cancer	Cerveau (SNC)
Phase	Phase II-III
Type étude	Clinique
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	
Investigateur principal	Dr David Mathieu
Coordonnateur	Mégane Lebel 819-346-1110 poste 14138
Statut	Actif en recrutement
But étude	Glioblastoma (GBM) adaptive, global, innovative learning environment (GBM AGILE) is an international, seamless Phase II/III response adaptive randomization platform trial designed to evaluate multiple therapies in newly diagnosed (ND) and recurrent GBM. Its goals are to identify effective therapies for glioblastoma and match effective therapies with patient subtypes. Bayesian response adaptive randomization is used within subtypes of the disease to assign participants to Arms based on their performance. The primary endpoint is overall survival (OS)GBM AGILE is designed to efficiently evaluate therapies. The trial will be conducted under a single Master Investigational New Drug Application/Clinical Trial Application and Master Protocol, allowing multiple drugs and drug combinations from different pharmaceutical companies to be evaluated simultaneously. The plan is to add experimental therapies as new information about promising new drugs are identified and remove therapies as they complete their evaluation.
Critères d'éligibilité	Newly Diagnosed Inclusion Criteria: • Age ≥ 18 years. • Histologically confirmed Grade IV GBM, inclusive of gliosarcoma (WHO criteria; IDH wild-type by immunohistochemistry [IHC] or sequencing for IDH) established following either a surgical resection or biopsy. An MRI scan with the required imaging sequences performed within 21 days prior to randomization preferably. The post-operative MRI scan performed within 96 hours of surgery or the MRI scan performed for radiation therapy planning may serve as the MRI scan performed during screening if all required imaging sequences were obtained. • Karnofsky performance status ≥ 60% performed within a 14-day window prior to randomization. • Availability of tumor tissue representative of GBM from definitive surgery or biopsy. Recurrent Inclusion Criteria: • Age ≥ 18 years. • Histologically confirmed Grade IV GBM, inclusive of gliosarcoma (WHO criteria; IDH wild-type by immunohistochemistry [IHC] or sequencing for IDH) at first or second recurrence after initial standard, control or experimental therapy that includes at a minimum radiation therapy (RT). • Evidence of recurrent disease demonstrated by disease progression using slightly modified Response Assessment in Neuro-Oncology (RANO) criteria. • Two scans to confirm progression are required: at least 1 scan at the time of progression and 1 scan prior to the time of progression. • Karnofsky performance status ≥ 70% performed within a 14-day window prior to randomization.

	• Availability of tumor tissue representative of GBM from initial definitive surgery and/or, recurrent surgery, if performed.
Critères d'exclusion	Newly Diagnosed Exclusion Criteria: • Received any prior treatment for glioma including: a. Prior prolifeprospan 20 with carmustine wafer. b. Prior intracerebral, intratumoral, or cerebral spinal fluid (CSF) agent. c. Prior radiation treatment for GBM or lower-grade glioma. d. Prior chemotherapy or immunotherapy for GBM or lower-grade glioma. Receiving additional, concurrent, active therapy for GBM outside of the trial. • Extensive leptomeningeal disease. • QTc > 450 msec if male and QTc > 470 msec if female. • History of another malignancy in the previous 2 years, with a disease-free interval of < 2 years. Patients with prior history of in situ cancer or basal or squamous cell skin cancer are eligible. Recurrent Exclusion Criteria: • Early disease progression prior to 3 months (12 weeks) from the completion of RT. • More than 2 prior lines for chemotherapy administration. (NOTE: In the 1st line adjuvant setting, combination of temozolomide (TMZ) with an experimental agent, is considered one line of chemotherapy.) • Received any prior treatment with lomustine, agents part of any of the experimental arms, and bevacizumab or other vascular endothelial growth factor (VEGF) or VEGF receptor-mediated targeted agent. • Any prior treatment with prolifeprospan 20 with carmustine wafer. • Any prior treatment with an intracerebral agent. • Receiving additional, concurrent, active therapy for GBM outside of the trial • Extensive leptomeningeal disease. • QTc > 450 msec if male and QTc > 470 msec if female. • History of another malignancy in the previous 2 years, with a disease-free interval of < 2 years. Patients with prior history of in situ cancer or basal or squamous cell skin cancer are eligible.